

Express Mail Label No. EV 409530457 US
Attorney Docket No. 6296.204-US
Serial No. 09/853,193; Filed: May 11, 2001

REMARKS/ARGUMENTS

Claims 1, 4, 7-14, 21-29 and 32-61 are pending.

Applicant respectfully requests that the Examiner initial and date the 1449 form submitted by Applicant on January 26, 2004 and attach it to the next communication mailed by the Patent Office.

Applicant also directs the Examiner's attention to co-pending application 10/359,324.

The amendments to the claims presented herein, and added claims 32-61, find support in the Examples and at page 3, lines 20-21 and page 7, lines 4-24 of the specification. While Applicant recognizes that entry of amendments after a final rejection is not a matter of right, Applicant respectfully requests entry of the amendments to the claims presented herein as they are believed to address the outstanding enablement rejection, do not add new matter and will not require any further search by the Examiner.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH

The Examiner rejected claims 1, 4-14 and 22-31 under section 112, first paragraph. In setting forth this rejection, the Examiner stated:

"the specification, while being enabling for a method for treating a critically ill patient or a critically ill polyneuropathy (CIPNP) patient comprising administering an amount of insulin as a blood glucose regulator effective to maintain blood glucose level in the patient in the range of about 60 mg/dL to about 130 mg/dL, or a method of treating a CIPNP patient comprising administering an amount of insulin as a blood glucose regulator effective to reduce the incidence of CIPNP and lengthen the time free of CIPNP in patients, does not reasonably provide enablement... where structure of the blood glucose regulator is not defined". (pages 3-4 of present Office Action).

While Applicant disagrees with the rejection and reserves the right to pursue the subject matter deleted from the claims in a continuation application, Applicant has, in the

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interests of advancing prosecution, limited the "blood glucose regulators" in the claimed methods to insulin, an insulin analogue, an active derivative of insulin or an insulin analogue, or a physiologically acceptable salt of said derivative. Thus, Applicant has limited the claimed methods to structurally defined blood glucose regulators (see page 7, lines 4-24 of the application) and accordingly, withdrawal of this rejection is respectfully requested.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

The Examiner rejected claims 4-14 as being indefinite for lacking an essential step in the method of treating a patient suffering from CIPNP; namely the outcome of such treatment. In particular, the Examiner alleges that "to treat CIPNP" does not indicate the effect of administering a glucose regulator in the treatment, eg., reducing the incidence of CIPNP and lengthening the time free of CIPNP in patients.

In reply, Applicant respectfully traverses this rejection.

Whether a claim is indefinite depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. Here, Applicant submits that those of skill in the art reading the claim in light of the present application would clearly understand whether a patient with CIPNP had been treated by the claimed method. Indeed, the Examiner notes that the application discloses that treatment of a CIPNP patient may be measured by criteria such as the reduction in the incidence of CIPNP and the lengthening of time free from CIPNP. Accordingly, Applicant submits that the phrase "to treat CIPNP" would have a clear and definite meaning to one skilled in the art and withdrawal of the section 112, second paragraph rejection is therefore respectfully requested.

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The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Please charge any deficiencies or overpayment to Deposit Account No.

14-1447.

Respectfully submitted,

Date: November 24, 2004


Richard W. Bork, Reg. No. 36,459
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

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